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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,784	09/15/2000	Malcolm L. Gefter	IMI-044DV3CN	3152

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EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/662,784	GEFTER ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95,96 and 101-104* is/are pending in the application.

4a) Of the above claim(s) *epitope species A-I, K-S* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95,96 and 101-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *95,96 and 101-104* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The Examiner and/or Art Unit of this U.S. Patent application has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1649.

2. The Election filed 8-12-05 has been entered into the record and has been fully considered.

3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

4. As a result of Applicants amendment, all rejections not reiterated herein have been withdrawn.

5. Claims 95-96 and 101-104 are pending.

Election/Restriction

6. Applicant's election with traverse of Group I, therapeutic compositions to the extent of SEQ ID NO:6, claims 95-96 and 101-104 in Paper No. 12 is acknowledged. Applicant's further election with traverse of epitope J, Fel 31-1 residues 33-59 in the paper of 8-12-05 is acknowledged. The traversal is on the ground(s) that the groups do not differ from each other but are similar in structure function and search and would not place undue burden upon the Examiner. Further Applicants argue that the epitiope portions share structural and functional features in that they are related to SEQ ID NO:6, that some epitopes share significant portions and that all can be used to reduce allergic responses to cat antigen. This is not found persuasive because the different SEQ ID NO:'s and portions define different in structural constraints in particular with

respect to epitopes and therefore are capable of different effects and usage. Because the searches are different each from the other the searches are not co-extensive and a search for a single member would not reveal all pertinent art to the other members. Further, it is noted that the search conducted for prior art pertinent to elected SEQ ID NO:6 reveals no similarity in hits to the alternative sequences of SEQ ID NO's 8, 10 and 16. Similarly the search for any eptiope portion does not necessarily constitute a search for any other and in addition different epitopes are recognized in the art as having distinct properties in stimulating immunity and immune responses. Rejoinder will only be considered upon the indication of allowable subject matter that is suitably linking.

The requirement is still deemed proper and is therefore made FINAL.

Priority

7. Applicant's have noted support based upon PCT/US90/06548 (filed November 2, 1990) for the full length sequence of SEQ ID NO: 6, as noted at least in Figure 3. For portion (b) of claim 95 Applicants elect species J, Fel31-1 residues 33-59 of SEQ ID NO:6. The amendment notes support for such portion within Table 3, pp. 48-49 of the specification. However, support is not found for such portion or an epitope containing portion within such residues. In particular Fel 31-1 appears to be epitope 14-40 as denoted in the figure. Similarly the recitation of such portions or epitope containing portions are not apparently supported from the specification as filed in 1990. Accordingly support and priority within the previous publications is not found, particularly for this species and therefore the effective filing date awarded instant claims is that of the instant filing date of 9-15-00 absent evidence for support.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 95-96 and 101-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6.019,972 and over claims 1-24 of U.S. Patent No. 5,547,669. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to the same peptide(s), emphasis plural thereby being a composition and mixture, comprised of portions or of full length SEQ ID NO:6. The recitations of "a therapeutic composition" are that of intended use and do not give further weight to any other element within the claim. Only the peptide is specified. Nevertheless the '972 cliams 9-26 are drawn to compositions as are the '669 claims 19-24. The properties of the peptides as recited in claim 102 are inherent as they are the same and a compound and its properties are inseparable. Claims 103-104 are directed to product by process limitations and do not distinguish over the products themselves. Accordingly the '972 and '669 claims anticipate or render obvious instant recitations.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 95-96 and 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Support is not found for the newly recited language with respect to elements b and c with respect to various Fel portions or epitope-containing portions. Most pertinently to the elected invention, support is not found for such epitope containing portion Fel 31-1 residues 33-59. It appears that this epitope was to epitope 14-40 as denoted in the figure at pp. 48-49 and not 33-59 as claimed. Accordingly the recitations constitute new matter.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 95-96 and 101-104 are rejected under 35 U.S.C. 102(b) and 102(e) as being anticipated by U.S. Patent No. 6,019,972 and U.S. Patent No. 5,547,669 (cumulative references).

The '972 and '669 patents are cumulative to instant application. Accordingly, the patnets are directed to full length SEQ ID NO:6, fragments and variants thereof differing in one or more amino acids and further noting particular eptiope compositions as in the disclosed SEQ ID NO's and peptides X, Y, and Z. The claims are directed to the same peptide(s), emphasis plural thereby being a composition and mixture, comprised of portions or of full length SEQ ID NO:6. The recitations of "a therapeutic composition" are that of intended use and do not give further weight to any other element within the claim. Only the peptide is specified. Nevertheless the '972 clams 9-26 are drawn to compositions as are the '669 claims 19-24. The properties of the peptides as recited in claim 102 are inherent as they are the same peptides and it is well established that a compound and its properties are inseparable. Claims 103-104 are directed to product by process limitations and do not distinguish over the products themselves. Accordingly the '972 and '669 claims anticipate the claimed invention. Priority is not granted, nor are teachings provided to the extent of the specific epitope of residues 33-59. However, the claims are not so limited.

13. Claims 95-96 and 101-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Leiterman et al., J. Allergy Clin. Immunol., 74:147-53, 1984, as evidenced by UniProt_03 alignment with accession No. P30440, April 1, 1993 as further evidenced by Harlow & Lane Cold Spring Harbor Labs, 1988, pp. 427.

Leiterman et al., teach Cat allergen 1:Biochemical, antigenic and allergenic properties. In particular the therapeutic composition of protein is provided in isolated form. The peptide is a part of a multi protein complex of various MW isoform, see in

particular abstract, and Material and Methods pp. 147-148 comprised therefore of a mixture. A peptide and its properties are inseparable, accordingly the peptide has the properties as noted in claim 102, the products being the same. Claims 103-104 are directed to product by process limitations and therefore do not distinguish over the peptide product. Harlow & Lane further teach that epitopes may be of only 4 or 5 amino acids, see in particular p. 427, lines 15-17. The accession notes identity in amino acid sequence in addition to the epitope of residues 31-57 corresponding with 100% identity to epitope of SEQ ID NO:6 residues 33-59. Thus, the reference teachings anticipate the claimed invention.

Status of Claims

14. No claims are allowed.

CONCLUSION

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

Sharon L. Turner, Ph.D.
October 31, 2005

SHARON TURNER, PH.D.
PRIMARY EXAMINER
10-31-05